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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/593,216	04/10/2007	Yasuhiko Takahashi	600630-58US	5928

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EXAMINER

VOGEL, NANCY TREPTOW

ART UNIT	PAPER NUMBER
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1636

NOTIFICATION DATE	DELIVERY MODE
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03/28/2011

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

usptomail@panitchlaw.com

Office Action Summary	Application No. 10/593,216	Applicant(s) TAKAHASHI ET AL.	
	Examiner NANCY VOGEL	Art Unit 1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 1/10/11.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13 and 16 is/are pending in the application.
- 4a) Of the above claim(s) 10-12 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9, 13 and 16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>11/30/10</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1-9, 10-13, 16 are pending.

Claims 10-12 are withdrawn.

Applicant's arguments regarding the requirement for election of species in the Office action mailed 12/9/10, have been found convincing, and the requirement is withdrawn.

Receipt of the Information Disclosure statement on 11/30/10 is acknowledged.

Any rejection of record in the previous action not addressed in this office action is withdrawn.

The following is a new rejection necessitated by applicants submission of the Information Disclosure Statement:

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-9, 13, 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Takahashi et al. (EP-A1-1 382 613) (cited by applicants) in view of Deeley et al. (US Patent 5,489,519) or Nakanishi (USPGPUB 20030157536) (cited by applicants).

Takahashi et al. disclose the a nucleotide sequence for the gene coding for Gm1, which is an alpha subunit of a G protein trimer (see claim 7 and SEQ ID NO:27 in

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particular). The difference between the reference and the instant claims is that the promoter region of said gene is provided, namely SEQ ID NO:1, and portions thereof which have promoter ability. However, the isolation of the promoter of an isolated gene was well known in the art, using standard practice, by such well known methods as using the 5' upstream region of a gene to isolate from a genomic library polynucleotides which are present in the upstream region of said gene, and test for promoter activity). Such methods are taught in the art, for example, by Deeley et al. (see col. 12, lines 3—53), where it is disclosed that “The intron-exon structure and the transcription regulatory sequences of the gene ...can be identified by using a nucleic acid of the invention to probe a genomic DNA clone library. Regulatory elements, such as promoter and enhancers necessary for expression of the gene can be identified using conventional techniques” and “The function of the elements can be confirmed by using them to express a reporter gene such as the bacterial gene lacZ, which is operatively linked to upstream fragments. Such a construct can be introduced into culture cells using standard procedures...”. The reference also discloses the promoter, linked to a gene, in a plasmid, and transformed into a cell. Furthermore Nakanishi et al. also teaches isolation of a promoter of a gene, isolated by isolating a genomic clone comprising 5' upstream region, linking the 5' region to a reporter gene, linking the construct to a plasmid and transforming into a cell, to test for promoter activity (Example 1-4). The reference also discloses a method for searching a substance having an ability to control activity of the promoter, comprising contacting the transformed cell with a test substance, monitoring expression amount of the reporter gene, evaluating ability of the

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test substance to control activity, and selecting the substance having ability to control transcription activity (Example 4-5, and claims). Therefore, the isolation and identification of the upstream transcription regulatory sequence, i.e. the promoter, of the known gene, and the assay for substances which control the activity, would have been obvious to one of ordinary skill in the art.

Conclusion

Applicant's submission of an information disclosure statement under 37 CFR 1.97(c) with the fee set forth in 37 CFR 1.17(p) on 11/30/10 prompted the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 609.04(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to NANCY VOGEL whose telephone number is (571)272-0780. The examiner can normally be reached on 7:00 - 3:30, Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joanne Hama can be reached on (571) 272-2911. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/NANCY VOGEL/
Primary Examiner, Art Unit 1636

NV
3/13/11